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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,540	01/28/2002	Ronald D. Russo	R-17	3722

7590

02/13/2003

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/058,540

Applicant(s)

RUSSO, RONALD D. *CR*

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 3 and 11-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. As to claim 3, it is unclear as to how the plunger functions as a wiper seal.
4. Claim 11 recites the limitation "the suction catheter assembly". There is insufficient antecedent basis for this limitation in the claim.
5. Claim 12 recites the limitation "said closing chamber" in line 10. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1, 2, 4-8, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Kee 6070582.

3. As to claims 1, 2, and 4-7 Kee teaches a suction system having a suction tube, a source of suction (col. 4, lines 25) and a suction control valve, the suction control valve comprising: a housing having an upper surface and a first central linear passageway; a second passageway opening at the upper surface and transversing the first central linear passageway; a manually depressible and releasable plunger, having a closed piston portion and an open lumen portion and is normally positioned in a non-suction applied position; means for preventing inadvertent depression of the plunger; a high flow cross lumen; a suction catheter; and actuator portion (see figures).

4. As to claims 8, Kee teaches a respiratory suction catheter system for suction secretions from a patient comprising: a frontal manifold; a rearward suction control valve adapted for attachment to a source of suction; a suction catheter; the suction control valve comprising: a housing having an upper surface and a first central linear passageway; a second passageway opening at the upper surfaces and transversing the first central linear passageway; a manually depressible and releasable plunger, having a close piston portion and an open lumen portion and is normally positioned in a non-suction applied position; and where the frontal manifold is fixedly connected to a suction catheter assembly (see figures).

5. Claims 12, and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by lund et al. 5598840.

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6. lund et al. teaches a respiratory suction catheter system for suction secretions from a patient comprising: a connector having front and rear ends; a cleaning chamber having an entrance opening; a catheter wiper and a catheter isolator seal having a slit opening; a suction catheter assembly having a housing; wherein the isolator seal is normally biased to a sealed position; wherein the isolator seal is operable to an open position solely by manual insertion of a suction catheter; and wherein the cleaning chamber includes an access port (see figures).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kee.

9. As to claim 11, Kee teaches the respiratory suction system of claim 8. It should be noted that Kee fails to specifically teach wherein the suction catheter assembly is disconnectable with the frontal manifold. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the assembly disconnectable, since it has been held that construction a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kee in view of lund et al.

11. Kee teaches the respiratory suction system of claim 8. It should be noted that Kee fails to specifically teach a means for cleaning the catheter.

12. lund et al. teaches a system with a common means for cleaning. Therefore it would have been obvious to one of ordinary skill in the art to modify the system of Kee to include the means for cleaning of lund et al. to clean the external catheter wall during retraction so as to minimize practitioner exposure to patient contaminants (col. 6, lines 18-21).

13. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over lund et al.

14. As to claims 13 and 14, lund et al. teaches the system of claim 12. It should be noted that lund et al. fails to teach a funnel shaped cleaning chamber. However, it would have been obvious to one of ordinary skill in the art to make the cleaning chamber of lund et al. funnel shaped because the shape of the cleaning chamber is a mere design choice and that any shape would perform equally well. Furthermore, the Applicant has not disclosed that the specific type of shape solves any stated problems or is for any particular purpose and it appears that the invention would perform equally well with the shape taught by lund et al.

15. Claims 20-28, 30-42, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over lund et al. in view of Kee.

16. lund et al. teaches the system of claim 12. It should be noted that lund et al. fails to teach a suction control valve.

17. Kee teaches a system with a common suction control valve for providing fluid flow control. Therefore it would have been obvious to one of ordinary skill in the art to modify the system of lund et al. to include the suction control valve of Kee to allow a suction catheter to remain positioned with the manifold without the necessity of attachment or detachment thereof between uses, thereby avoiding substantial manifold pressure loss (col. 1, lines 48-51).

18. lund/Kee teaches the system of claim 20 including a catheter isolator seal between the frontal manifold and the suction catheter that is 100% normally sealed air tight; wherein the isolator seal is opened by contact with the distal tip of the suction catheter; a cleaning chamber including a catheter wiper and a catheter cleaning flush port; wherein the suction catheter is fixed attached to the frontal manifold; wherein the catheter assembly is disconnectable from the frontal manifold; and including a sleeved catheter (see figures).

19. As to claims 34-42 and 44, lund/Kee teaches a respiratory suction catheter system for suctioning secretions from a patient comprising: a frontal manifold having an upstream and downstream ends; a catheter cleaning chamber having proximal and distal ends and an entrance opening; a catheter wiper and a catheter isolator seal; a suction catheter assembly; a catheter with a distal tip end and a proximal end; wherein the suction catheter is fixed attached to the frontal manifold; wherein the catheter assembly is disconnectable from the frontal manifold; wherein the catheter is enclosed in a collapsible sleeve; wherein the catheter is attached to a source of suction; wherein the catheter is attached to a normally closed suction control valve; wherein the cleaning

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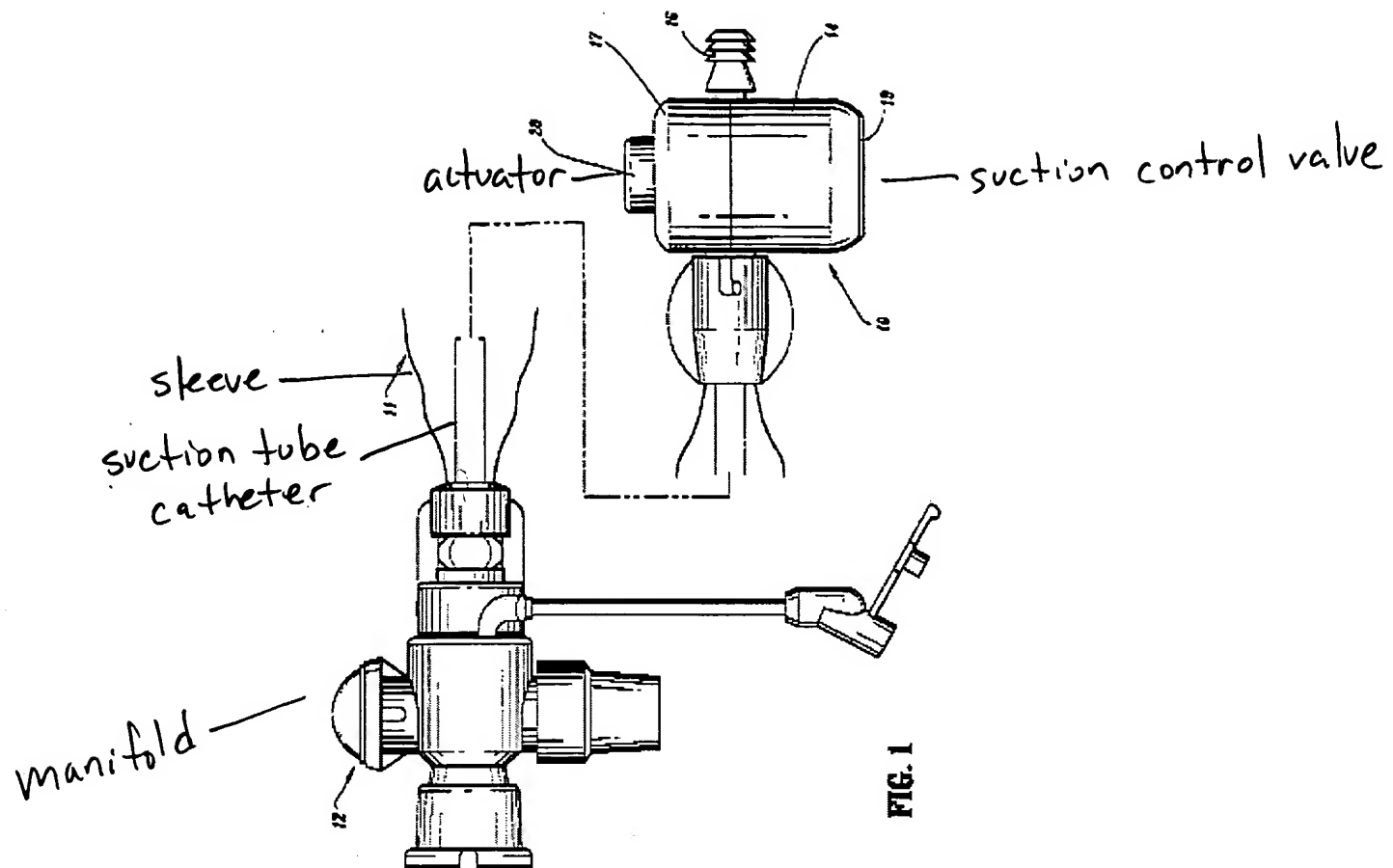
chamber includes an access port; wherein the access port is a catheter cleaning flush port; and wherein the access port is fully capable of being a combination lavage, medication delivery and catheter flush port.

20. Claims 29 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over lund et al. in view of Kee in further view of Kee et al. 5738091.

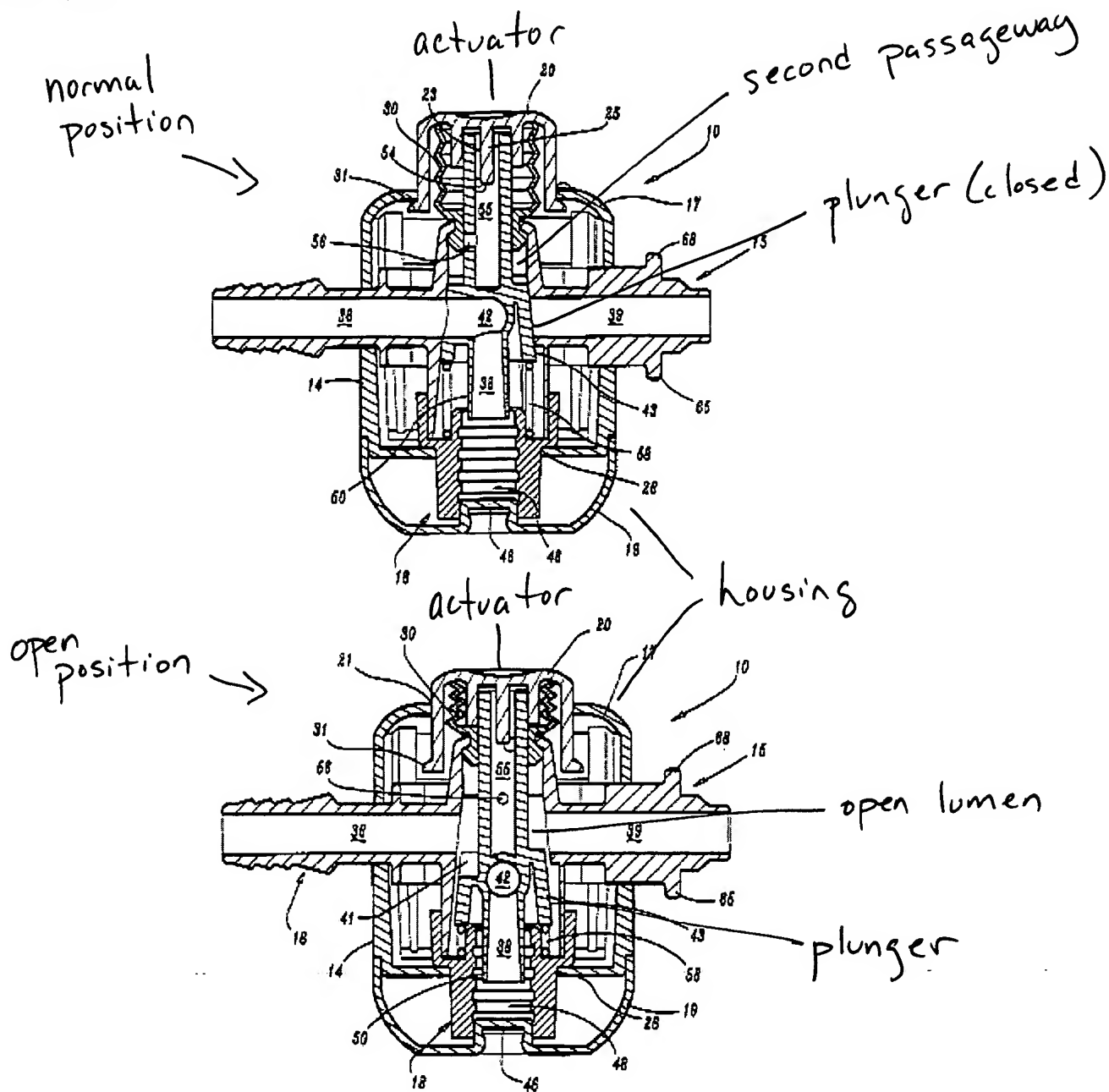
21. As to claim 29 and 43, lund/Kee teaches the systems of claim 28 and 34. It should be noted that Lund/Kee fails to specifically teach wherein the catheter cleaning flush port includes a one-way valve.

22. Kee et al. teaches a system with a common one-way valve allow fluid to be injected into the port. Therefore it would have been obvious to one of ordinary skill in the art to modify the system of lund/Kee to include the one-way valve of Kee et al. to allow fluid to be injected into the port, but inhibit fluid flow in the opposite direction (col. 9, lines 7-12).

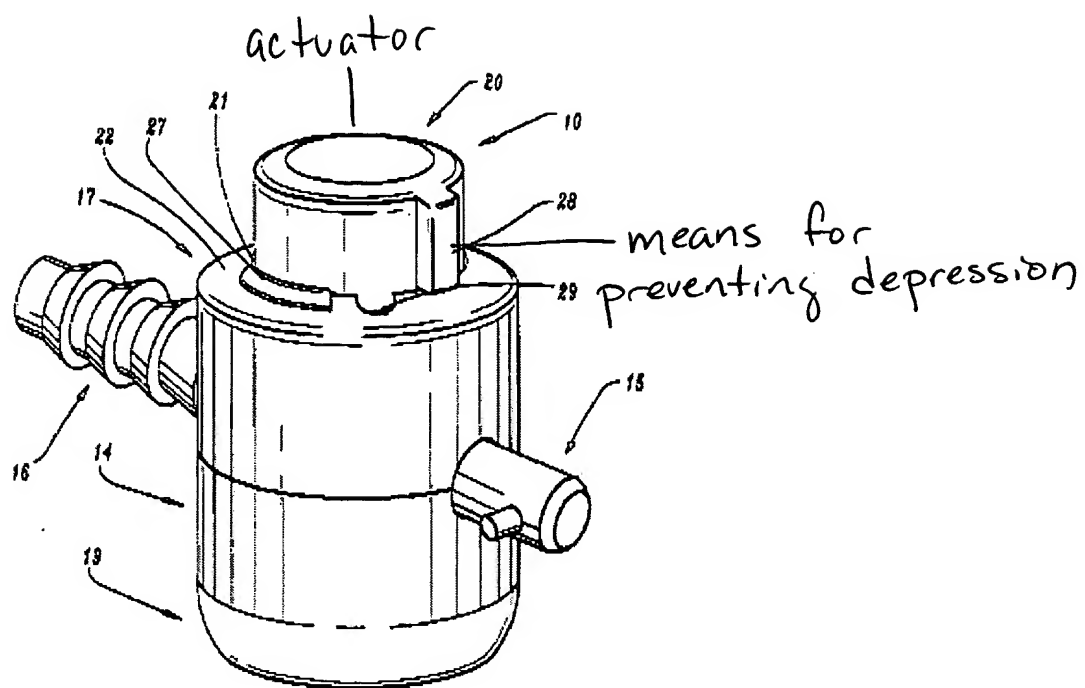


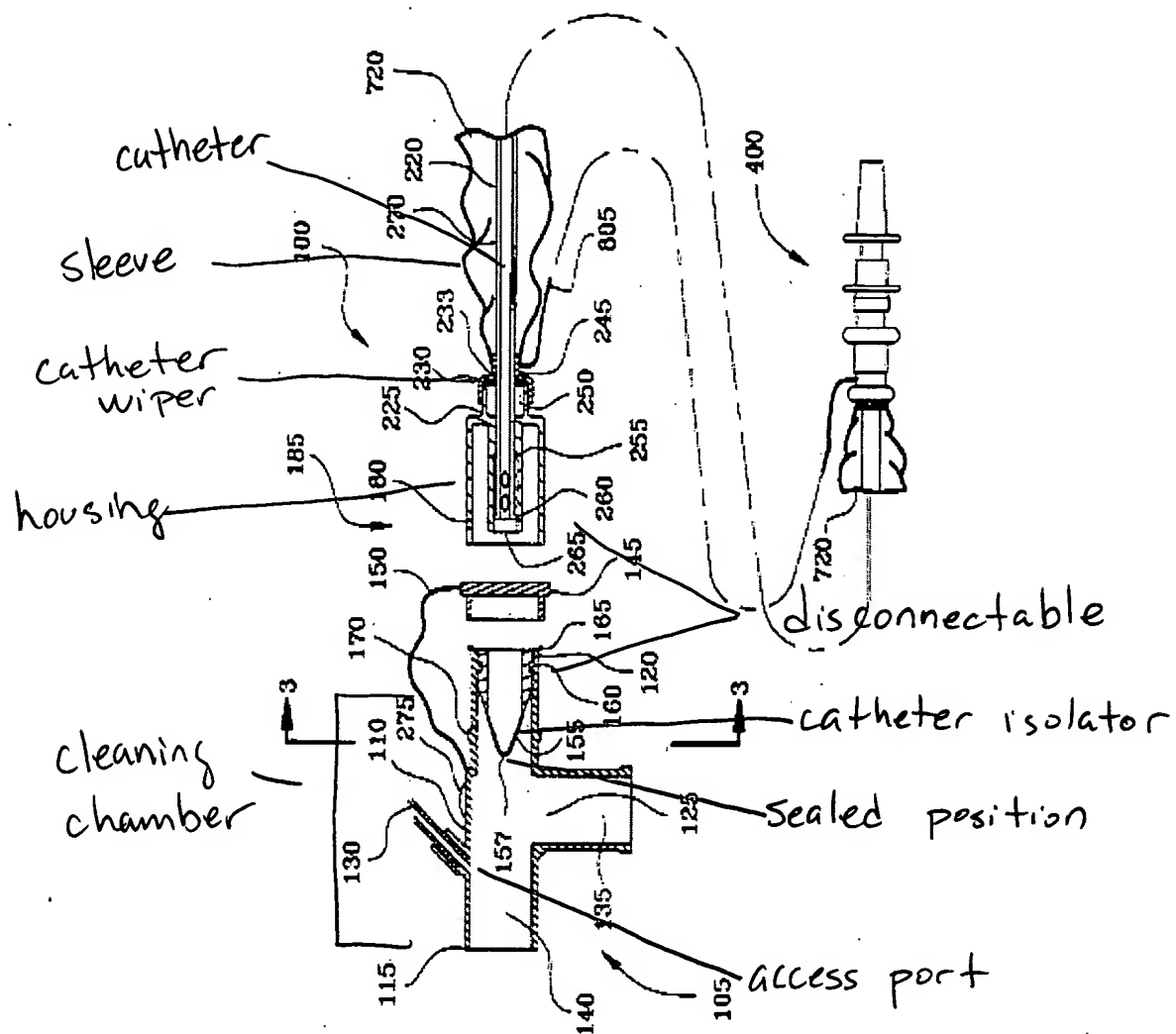


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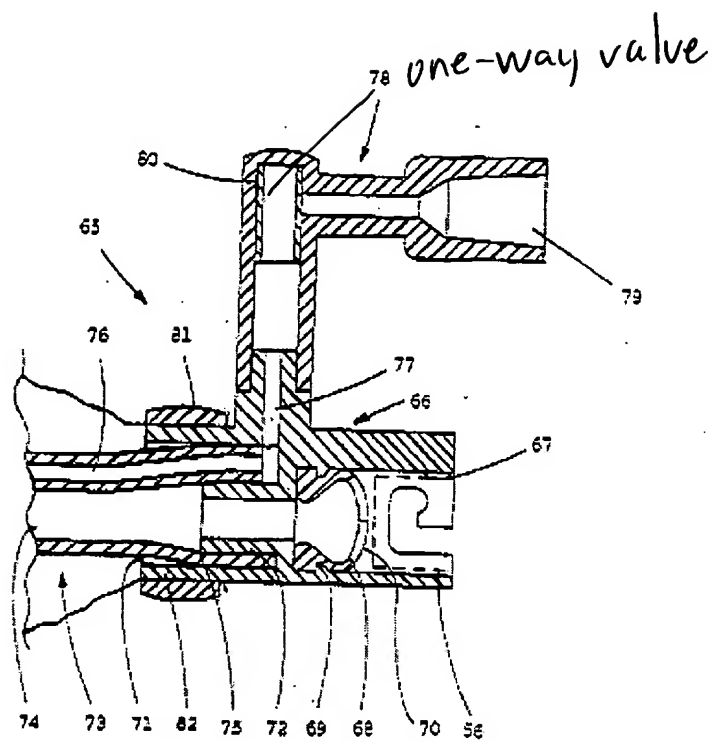


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**Contacts**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

mmh

MM  
February 6, 2003

  
**GLENN K. DAWSON**  
**PRIMARY EXAMINER**